بسم الله الرحمن الرحيم

قال تعالى :

{ لاَ يُكَلِّفُ اللَّهُ نَفْسًا إِلاَّ وُسْعَهَا لَهَا مَا كَسَبَتْ وَعَلَيْهَا مَا اكْتَسَبَتْ رَبَّنَا لاَ تُؤَاخِذْنَا إِن نَّسِينَا أَوْ أَخْطَأْنَا رَبَّنَا وَلاَ تَحْمِلْ عَلَيْنَا إِصْرًا كَمَا حَمَلْتَهُ عَلَى الَّذِينَ مِن قَبْلِنَا رَبَّنَا وَلاَ تُحَمِّلْنَا مَا لاَ طَاقَةَ لَنَا بِهِ وَاعْفُ عَنَّا وَاغْفِرْ لَنَا وَارْحَمْنَا أَنتَ مَوْلانَا فَانصُرْنَا عَلَى الْقَوْمِ الْكَافِرِينَ }

صدق الله العظيم

سوره البقره الآيه ((286))

Dedication

To my **mother** the reason of what I become today. Thanks for your great support and continuous care.

To my **brother** and sisters.

To soul of my supervisor khalda, Order all the love and respect for her.

To all who make the effort and contribution for me my **Colleagues**

To all the above mention and all whom help me to make this work I dedicate this work.

Acknowledgments

Thanks for my god Allah firstly and lastly, enabled me to conduct this study by his blessing therefore great thanks for my family which always encourage me, the better thanks for my friends, who helped me and made me going on.

Thanks for my supervisor, who guide me on this research and last thanks for everyone who helped me in my research.

Abstract

This was a prospective and cross sectional study conducted in Hi Tech Laboratory, Dr. Mohammed Altaib Laboratory and Modern Medical Laboratory during the period from February to August 2016 .The study was performed to determine the complete blood count using three different Automated hematology analyzers and aimed to compare between this machines, fifty blood samples were collected in EDTA container (2.5ml) , CBC estimation was carried by sysmex kxn-21, Digon D cell-60 and URIT 3010 hematological analyzers and the results were analyzed using Statistical package for Social Science computer program, Mean ± SD and One way Anova test were used (*p.value* >0.05) ,Sensitivity and Specificity also were measured.

The results indicated that there was significant correlation in the mean of Hb, RBC, HCT, MCV, MCHC, RDW-CV , WBCs ,Neutrophil ,MIX (monocyte ,eosinophil ,basophil), MPV ,PDW and PLCR *P. value* <0.05 , while there was insignificant correlation in means of MCH ,RDW-CV ,Lymphocyte and PLT *P. value* ≥0.05.

Sysmex kxn-21 hematological analyzer found to be more sensitive and specific when using in measurement of Hb , RBC, HCT ,MCV, MCHC, RDW-SD compared with Digon D cell-60 and URIT 3010 hematological analyzers ,while URIT 3010 hematological analyzer was more sensitive and specific when using in measurement of WBCs, Lymphocyte, Neutrophil ,MIX count, PLT, MPV,PDW compared with them.

The study concluded that both Sysmex kxn-21 and URIT 3010 hematological analyzers were more sensitive and specific in measurement of CBC.

مستخلص البحث

هذه دراسة مقطعية احتماليه أجريت في معمل هاي تك ، ومعمل د. محمد الطيب للتحاليل الطبيه والمعمل الطبي الحديث خلال الفترة من فبراير إلى أغسطس 2016 . هدفت هذه الدراسه لقياس تعداد الدم الكامل باستخدام ثلاثة اجهزه اليه مختلفة لتحليل قياس الدم و المقارنة بين هذه الآجهزه المختلفه ،تم اخذ خمسين عينه دم في حاويه تحتوي علي ماده مانعه للتجلط EDTA ومقدارها 2,5مل , فحصت صور الدم الكامله باستخدام الاجهزه Sysmex kxn-21, Digon D cell60 و URIT 3010 وقد حللت النتائج بواسطه الحاسب الالي باستخدام برنامج الحزم الاحصائيه للمجتمع SPSS القيمه الاحتماليه اقل من 0.05 وايضا قيست حساسيه وخصوصيه الاجهزه.

وأشارت النتائج إلى أن هنالك ارتباط كبير في متوسط خضاب الدم , كريات الدم الحمراء, متوسط حجم الخليه الحمراء, نسبه خضاب الدم في الخليه الحمراء, نسبه انتشار الخلايا الحمراء, عدد كريات الدم البيضاء, الخلايا العدله, الخلايا المختلطه البيضاء, انتشار الصفائح الدمويه و متوسط حجم صفيحه الدم الواحده في القيمة الاحتماليه <0.05 . في حين كان هناك ارتباط ضئيل في متوسط انتشار الخلايا الحمراء, نسبه الخلايا الليمفاويه ,الصفائح الدمويه بقيمه احتماليه اكبر من او تساوي 0.05

جهاز تحليل الدم Sysmex kxn-21 وجد انه اكثر حساسيه وخصوصيه عند استخدامه في قياس خضاب الدم، عدد خلايا الدم الحمراء، كليات التقنية العليا، متوسط حجم الخليه الحمراء ,نسبه خضاب الدم في الخليه الحمراء، نسبه انتشار الخلايا الحمراء مقارنه مع اجهزه تحليل الدم Digon D cell60 و URIT3010 . جهاز تحليلURT3010 اكثر حساسيه وخصوصيه عند استخدامه في قياس الكريات البيضاء، الخلايا الليمفاوية، الخلايا العدله، الخلايا المختلطه الاعتماد، الصفائح الدمويه، انتشار الصفائح الدمويه، متوسط حجم صفيحه الدم الواحده مقارنه معهم.

وخلصت الدراسه الى ان كلا من Sysmex kxn-2 و URIT3010 كانت اكثر حساسيه وخصوصيه في قياس وفحص تعداد الدم الكامل.

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Abbreviations

ANC	Absolute Neutrophil Count
CBC	complete Blood Cell
DLC	Differential Leukocyte count
EDTA	Ethyline diamine tetra acetic acid
FBC	Full Blood Cell
FBE	Full Blood exam
fl	Fimtoliter
g/dl	Gram per Deciliter
Hb	Hemoglobin
Lymph	Lymphocyte
MCV	Mean corpuscular volume
MCH	Mean corpuscular Hemoglobin
MPV	Mean Platelet Volume
MCHC	Mean corpuscular Hemoglobin Concentration
Neutro	Neutrophil
NK	Natural Killer cell
PCV	packed cell volume
PDW	Platelet Distribution width
PLT	Platelet

PLCR	Platelet large Cell Ratio
Pg	Pictogram
QC	Quality control
RBC	Red blood cell
RDW-CV	Red Distribution width by Coefficient of variation
RDW-SD	Red Distribution width by Standard Deviation
WBC	White Blood cell

Chapter one

Introduction and Literature Review

Chapter one

Introduction and Literature Review

1.1 Introduction

Management of patients with hematological disorders has become increasingly arduous. Requiring the hematologist to acquire unique clinical skills; conversely. Major developments in laboratory practice require a high level of technical expertise. Especially in handling automated instruments and information technology (Hoffbrand *et a1.*,1999).

The complete blood count (CBC) and differential leukocyte count (DLC) are the backbone of any laboratory evaluation, not only used by general practitioners, but also by other medical specialties. They provide valuable information about the blood and to some extent about the bone marrow, which is the blood-forming tissue. The CBC and DLC are used to diagnose anemia, to identify acute and chronic illnesses, bleeding tendencies, and white blood cell disorders, for example leukemia. During the last quarter century, blood cell analysis has progressed from the use of labor-intensive manual procedures to the use of highly automated instruments. Modern hematology analyzers provide new additional parameters enabling earlier and more precise diagnosis. Moreover, therefore it is crucial that obtained parameters are clear for clinicians, and the results completely used (Chapman, 2000).

Hematology instrument operations consist of computation, CBC analysis, and other analyses such as DLC. On many large analyzers, the on board computer does computation, analysis; it controls all hardware and software operations, and

contains a database of stored patient data and quality control results (Koenn *etal*,.2001) Some instruments have incorporated sophisticated features such as delta-checking of data from the same patient, and the displaying of electronic cell-sizing data via multi-color scatter gram plots. (Chapman, 2000).

1.2 Literature review

1.2.1Quality control

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting. (WHO, 2011)

Laboratories produce test results that are widely used in clinical and public health settings, and health outcomes depend on the accuracy of the testing and reporting. In order to achieve the highest level of accuracy and reliability, it is essential to perform all processes and procedures in the laboratory in the best possible way (WHO, 2011).

1.2.2 Quality control in hematology

A quality control (QC) protocol for hematology, as for other sections of the laboratory, should encompass both internal and external QC programs. The extent to which a hematology laboratory should be involved depends upon various factors, including availability of facilities, financial resources, range of tests, workload, the number of staff and their levels of training, and the overall organization of the laboratory. To ensure quality patient care, the intra laboratory QC program must include at least the minimal measures of monitoring and control at each step from collection of blood specimens, through the actual processing and analysis, to reporting of the results.(Gulati *et al.*,1986).The protocol should be written concisely and in simple language the procedure manual should offer all of the pertinent information along with references; all concerned personnel should be well trained and competent; and adequate facilities and time should be available

for the purpose of QC. Continuing education is also an integral part of an effective QC program. (Gulati *et al.*, 1986) Three very important aspects of QC in hematology are calibration of automated instruments, monitoring of accuracy and precision of instruments and procedures, and verifying the reliability of test results. For calibration of instruments for the CBC, the most commonly performed hematologic test, the use of commercial calibrators is acceptable. A combination of commercial controls (three levels) and retained or fresh patient blood specimens is recommended for monitoring of accuracy and precision on a long- and short-term basis.(Gulati *e tal.*,1986). Patient red-cell indices allow continuous monitoring of instrument performance and should be used as an adjunct to other QC approaches to detecting instrument calibration drift. Correlation of results of related parameters and careful review of blood films remain the two most important and widely used approaches to ensure reliability of results obtained from automated hematology instruments. Participation in an external QC program offers the most practical means of monitoring overall work performance in comparison with instrument, method, and/or reagent-based peer group data. A laboratory may choose to participate in one or more national and or regional QC programs, depending upon the range of tests it performs and the requirements of accreditation and regulatory agencies. Most of the accreditation agencies require participation in programs covering at least all of the routinely or frequently performed tests and, if available, also in those for infrequently performed tests.(Gulati *et al.*,1986)

1.2.3 Complete Blood Count CBC

A complete blood count (CBC), also known full blood count (FBC), or full blood exam (FBE), that gives information about the Blood cells, such as the cell count for each cell type and the concentrations of various proteins and minerals. The cells that circulate in the blood stream are generally divided into three types white blood cells (leukocyte), red blood cells (erythrocytes) and (thrombocytes). (Gomella,2013).

Abnormally high or low counts may indicate the presence of many forms of disease, and hence blood counts are amongst the most commonly performed blood tests in medicine, as they can provide an overview of a patient's general health status.(Gomella,2013).

1.2.3.1 Hemoglobin

Hemoglobin is the molecule responsible for the transport of oxygen. Under physiological conditions, three types of hemoglobins

•Hemoglobin A ($\alpha 2\beta 2$): major adult hemoglobin (96–98%).

• Hemoglobin F ($\alpha 2\gamma 2$): predominant during fetal development,60–80% at birth,0.5–0.8% during adult life.

• Hemoglobin A2($\alpha 2\delta 2$): normally 1.5–3%. The hemoglobin molecule has a molecular weight of 64,500 and consists of four polypeptide chains, each carrying a hem group. The hem synthesis starts with the amino acid glycine. (Reinhold Munker *et al*.,2007)

1.2.3.2 Red Blood Cell

Red blood cells are specialized cells that deliver oxygen to tissues and remove carbon dioxide from the human body. Erythropoiesis, the “making of red cells" involves many different genes and gene products that lead to the production of the mature cell. Red cells remain viable and functional for an average of 120 days.(Reinhold Munker *et al*.,2007).

1.2.3.3 Hematocrit

The packed cell volume (PCV) can be used as a simple screening test for anemia, as a reference method for calibrating automated blood count systems and as a rough guide to the accuracy of hemoglobin measurements. It can be used in the calculation of red cell indices in conjunction with estimations of Hb and RBC. (Bain, 2004)

1.2.3.4 Red cell indices

Provide information about the hemoglobin content and size of red blood cells. Abnormal values indicate the presence of anemia and which type of anemia is it.(Henry ,2011)

1.2.3.4. 1Mean corpuscular volume

MCV is the average size of a red blood cell and is calculated by dividing the PCV by the red blood cell count MCV= PCV/RBC×10 Normal range; 80-100 fL. (Henry ,2011)

1.2.3.4.2Mean corpuscular hemoglobin

MCH is the average amount of hemoglobin

MCH= HB/ RBC ×10

Normal range: 27-31 Pg. (Henry, 2011)

1.2.3.4.3Mean corpuscular hemoglobin concentration

Is the average concentration of hemoglobin per unit volume of red blood cell and is calculated by HB / HCT× 100

Normal range: 32-36%. (Henry ,2011)

1.2.3.5 Red Cell distribution Width

Red cell distribution width is a measure of the variation of red blood cell volume that is reported as part of CBC usually red cell is standard size of about 6-8 micrometer in diameter. Higher RDW values indicate greater variation in size .Normal range is 11.5- 14.5 %. RDW can give of early change in RBCs which is combined in iron deficiency anemia.(Turgeon,2010).

1.2.3.6 White Blood Cell

Several types of leukocytes, or white blood cells (WBCs), are found in the blood. The normal WBC count is 4,000 to 10,000/L Leukocytes are usually divided into granulocytes, which have specific granules, and a granulocytes, which lack specific granules. Granulocytes are divided into neutrophils (with faintly staining granules), eosinophils (with large reddish or eosinophilic granules), and basophils
(with large dark blue or basophilic granules). A granulocytes are divided into lymphocytes and monocytes.

Although they are called white blood cells, leukocytes predominantly
function in tissues. They are only in the blood transiently, while they travel
to their site of action.(William *et al*.,2002).

1.2.3.6.1 Neutrophil

Neutrophils are the most common type of WBCs in adults, the primary function of neutrophils is phagocytosis, predominantly of bacteria; neutrophils are the primary defense against bacterial infection.

Bacteria are killed by antimicrobial agents contained or generated within neutrophil granules. Neutrophils circulate in the blood for ~10 hours and may live 1 to 4 days in the extravascular space. The trip is one way; once neutrophils leave the blood to enter tissues, they cannot return. A significant number of neutrophils are rolling along the endothelial surface of blood vessels (the marginating pool). This population can be rapidly mobilized with acute stress or infection. (William *et al*.,2002)

1.2.3.6.2 Eosinophil

Eosinophils contain large granules that stain reddish-orange (eosinophilic) with usual blood smear stains. The nucleus is segmented often bilobed. Functions of eosinophils include phagocytosis of antigen-antibody complexes and defense against parasitic infection. The normal eosinophil count is ~2 to 4% of total WBC. The number of eosinophils increases with allergic reactions and parasitic infections (William *et al*.,2002)

1.2.3.6.3 Basophil

Basophils contain large dark blue or purple (basophilic) granules, which often obscure the nucleus. The nucleus is segmented. Basophils are the least common type of leukocytes, normally ≤1% of total WBCs. The basophil granules contain heparin (an anticoagulant), histamine (a fast vasodilator), the slow-reacting substance of anaphylaxis (a slow vasodilator), and other compounds. Basophils appear to be involved in immediate hypersensitivity reactions related to immunoglobulin class E (IgE). (William *et al*.,2002)

1.2.3.6.4 Lymphocyte

Lymphocytes are the second most numerous circulating white cells after neutrophils. They are divided into three functional types: B cells, T cells and natural killer (NK) cells. B cells differentiate in tissues into plasma cells, which

secrete antibodies, T cells function in cell-mediated immunity as do (NK) cells.(Bain,2004).

1.2.3.6.5 Monocytes

Monocytes are the largest normal blood cells. The function mainly in tissues where they differentiate into long-lived macrophages (sometimes called histocytes).They are part of the body's defenses against bacterial and fungal infections and also ingest and break down dead and dying body cells.(Bain,2004).

1.2.3.7Blood Platelets

Also called thrombocytes, are a component of blood whose function (along with the coagulation factors) is to stop bleeding by clumping and clogging blood vessel injury. Platelets have no cell nucleus, they are fragments of cytoplasm which are derived from the megakaryocytes of the bone marrow, and then enter the circulation. The main function of platelets is to contribute to hemostasis. (Berger *et al.*, 2008).

1.2.3.7.1 platelet distribution Width

Platelets distribution width median was 13.3%, with a reference range of 10-17.9% .among all indices PDW receiving attention due to its usefulness for distinguishing between reactive thrombocytosis associated with myeloproliferative disorder.(Turgeon,2010).

1.2.3.7.2 Mean platelet volume (MPV)

The mean platelet volume (MPV) is derived from the impedance platelet size distribution curve. The MPV is lower than predicted when thrombocytopenia is caused by megaloblastic anemia or bone marrow failure an increase in MPV has

been observed in patients at risk of and following myocardial infarction and cerebral infarction. MPV is the average volume of individual platelets derived from the Plt histogram. It represents the mean volume of the Plt population under the fitted Plt curve multiplied by a calibration constant, and expressed in femtoliters. (Dacie and Lewis, 2011).

1.2.4 Method and technique for CBC determination

1.2.4.1 Automated blood count technique

A variety of automated instruments for performing blood counts are in widespread use. Semi automated instruments require some steps (e.g. dilution of a blood sample) to be carried out by the operator. Fully automated instruments require only that an appropriate blood samples presented to the instrument. Semi automated instruments often measure a small number of components (e.g WBC and Hb). Fully automated multichannel instruments usually measure from 8 to 20 components for the basic CBC and white blood cell differential, including some variables that have no equivalent in manual techniques .Automated instruments usually have a high level of precision, which, for cell counting and cell-sizing techniques, is greatly superior to that achievable with manual techniques.(Dacie and Lewis,2011). If instruments are carefully calibrated and their correct operation is ensured by quality control procedures, they produce test results that are generally accurate. Blood cell counters may have automated procedures for sample recognition (e.g. by bar-coding), for ensuring that adequate sample mixing occurs, for taking up the test sample automatically and for detection of clots or in adequately samples sized. Ideally, blood sampling is carried out by piercing the cap of a closed tube so that samples that carry an infection hazard can be handled with maximum safety. Laboratories performing large numbers of blood counts

each day require fully automated blood counters capable of the rapid production of accurate and precise blood counts, including platelet counts and differential counts, either three-part or five- to seven-part. The sample throughput required varies with the workload and the timing of arrival of blood specimens in the laboratory, but for most large laboratories, a throughput of100 or more samples per hour is required. Sample size and the availability of a 'predilute' mode are particularly relevant if the laboratory receives many pediatric specimens.(Dacie and Lewis,2011).

1.2.4.2 Counting systems

1.2.4.2.1 Impedance Counting

Impedance counting, first described by Wallace Coulter in1956, depends on the fact that red cells are poor conductors of electricity, whereas certain diluents are good conductors; for a cell count, blood is highly diluted in a buffered electrolyte solution. The flow rate of this diluted samples controlled by a mercury siphon or by displacement of a tightly fitting piston. This results in a measured volume of the sample passing through an aperture tube of specific dimensions . By means of a constant source of electricity, a direct current is maintained between two electrodes, one in the sample beaker or the chamber surrounding the aperture tube and another inside the aperture tube. As a blood cell is carried through the aperture, it displaces some of the conducting fluid and increases the electrical resistance. This produces a corresponding change in potential between the electrodes, which lasts as long as the red cell takes to pass though the aperture; the height of the pulses produced indicates the volume of the cells passing through. The pulses can be displayed on an oscillo graph screen. The pulses are led to a threshold circuit provided with an amplitude discriminator for selecting the minimal pulse height, which will be counted The height of the pulses is used to determine the volume of the red cells.(Dacie and Lewis,2011).

1.2.4.2.2 Light Scattering

Red cells and other blood cells may be counted by means of electro optical detectors .A diluted cell suspension flows through an aperture so that the cells pass, in single file, in front of a light source; light is scattered by the cells passing through the light beam. The scattered light is detected by a photomultiplier or photodiode, which converts it into electrical impulses that are accumulated and counted. The amount of light scattered is proportional to the surface area and therefore the volume of the cell so that the height of the electrical pulses can be used to estimate the cell volume. The high-intensity coherent laser beams used in current instruments have superior optical qualities to the non coherent tungsten light of earlier instruments. Sheathed flow allows cells to flow in an axial stream with a diameter not much greater than that of a red cell; light can be precisely focused on this stream of cells. Electro-optical detectors are used for red cell sizing and counting in Siemens (previously Bayer-Technicon) systems and for white cell differential counting in a number of other instruments.(Dacie and Lewis,2011).

1.2.4.3Sysmex KX-21N Automated Hematology Analyzer

With its simplified operation, the KX-21N is an ideal hematology analyzer for a clinic laboratory or research testing. It provides a CBC with 17 reportable parameters and 3-part WBC Differential, which includes an Absolute Neutrophil Count (ANC). The results include histograms for WBC, RBC and PLT. The system provides a high level of accuracy through the use of automatic floating discriminators. Built on reliable Sysmex technology, it features a simple start-up menu and single button selection for sampling and daily maintenance with a compact, space-saving design.(SYSMEX CORPORATION,SN: B7627).

1.2.4.3.1 Feature and benefits Reliability, Accuracy and Simplicity

- Same direct current detection method as Sysmex high-end systems to provide accurate, comparable results
- Minimal training required
- Simple menus
- Push button technology
- Non-toxic, biodegradable reagents

. Reliable hard ware and results.

1.2.4.3.2 Specification Simple, Compact and Reliable

Whole blood mode: have 17 parameters with 3-part Differential Pre-dilute mode: 8 parameters, which includes WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT

. WBC, RBC, PLT histogram

.volume for Whole blood mode: 50 µL and for Pre-dilute mode: 20 µL

.Storage data about 300 complete sample results with histograms

.Whole Blood Linearity for WBC: 1.0 - 99.9 x 10^3/µL , RBC: 0.30 - 7.00 x 10^6/µL PLT: 10 - 999 x 10^3/µL.

1.2.4.3.3. Technology

White Blood Cells, Red Blood Cells and Platelets - WBCs, RBCs and PLTs are counted using the direct current detection method with coincidence correction.

Automatic discriminators separate the cell populations based on complex algorithms. The intensity of the electronic pulse from each analyzed cell is proportional to the cell volume. The hematocrit (HCT) is directly determined based on the red cell count and volume detection of each individual RBC. Even with samples at extremely low or unusually high concentrations, the Sysmex cell counters analyze WBCs, RBCs and PLTs with uncompromised precision and accuracy.

Hemoglobin Analysis - Hemoglobin analysis is conducted using a non-cyanide method.(SYSMEX CORPORATION,SN: B7627).

1.2.4.4Digon D cell 60 hematology analyzer

1.2.4.4.1 Feature and benefits

- Full blood picture from venous or capillary blood
- Automatic cleaning programs
- Low reagent consumption, cost effective operation
- Low sample volume
- High reliability
- Maintenance free concept

1.2.4.4.2 Specification

19 parameters and 3-part differentiation of WBC and Histogram for WBC, RBC,PLT Sample Volume for Prediluted 20 uL blood, Whole blood 13 uL

Principles Electrical resistance for cell counting and Cyanide free

method for hemoglobin Automatic orifice clearing Huge number of sample results, including histograms can be stored Built-in thermal printer (optional external printer) Bar code scanner (optional) Touchpad and normal computer keyboard for convenient data entry Large color LCD display whole blood linearity for WBC 0.0-99.910^9/L, RBC 0.00-9.99 10^{12}/L, Hb 0-300 g/l MCV 40.0-150.0fl PLT 10-999 $l0^9$/L.

1.2.4.4.3 Technology

A sample volume of a whole blood specimen is aspirated into the analyzer where a portion of it is automatically diluted with Diaton-D-Diluent. A portion of this first dilution is further diluted with Diaton-D-Diluent. This second dilution of the sample is then introduced into impedance particle analyzer where the red blood cell counts (RBC) and the thrombocyte count (PLT) is measured. To the remainder of the first dilution a lysing reagent (Diaton-Lyse-D) is added for the measurement of hemoglobin (HGB), white blood cell count (WBC), lymphocytes count (LYM), mid cell (MID), granulocyte count (GRAN).(Digon Ltd SN:AC76AA2201)

1.2.4.5 Hematology Analyzer (URIT-3010)

1.2.4.5.1 Feature and benefits

- Large color LCD display and Linux operating system
- Support USB data backup and system upgrade
- Excellent data management with mouse and keyboard
- High efficient self-checking system and low maintenance
- Support LIS and HIS with HL7 protocol
- Collaborator of BIO-RAD control target value available.

1.2.4.5.2 Specification

Parameters: 19 Parameters WBC, LY#, MO#, GR#, LY%, MO%, GR%, RBC, HGB, HCT, MCV, MCH, MCHC,RDW-CV, RDW-SD, PLT, MPV, PDW, PCT 3-part differentiation of WBC, and 3 histogram Principles of operation: WBC /RBC /PLT : Electrical Impedance

HGB: Photo electric colromitry
Aspiration Volume: Whole blood 18μL, Pre-diluted 20μL
Throughput: 60 samples per hour
Data storage: More than 100, 000 sample results with histograms
Alarms: Errors messages
Dilution Ration: Whole blood Capillary blood
WBC/HGB 1: 232 1: 400
RBC/PLT 1: 40000 1: 45000
Input / Output: Support RS232, standard network port and USB Built-in thermal printer, optional external printer

1.2.4.5.3Technology

The cell are counted and size by electrical impedance method based on measurement of changes in electrical current which are produced by particle ,suspended in conductive liquid ,as it passes through an aperture of known dimensions. the HB is measure by colorimetric method ,lyse added into the blood sample crack the membrane of RBCs promptly and transfer into compound which can adsorb the wavelength 540 nm and compare with pure diluent and sample .the concentration of sample hemoglobin is calculated. The others parameters derived

by calculation from certain formula. (URIT Medical Electronic Co.Ltd SN: 3010E01744).

1.2.5 Previous study

1..2.5.1 Previous study in world

Hux l and *et al.*, 2002 showed That maximum coefficients of variation (CVs. %) among three main manufacturers of hematology analyzer (SysmexKxn-21, Digon d-cell60,and other different manufacture) of red blood cell count (RBC), hemoglobin Hb), hematocrit (Hct), white blood cell count (WBC) and platelet count (Plt) were 3.2%, 3.8%, 3.6%9.3% and 10.8%, respectively. The maximum deviations among these parameters of different instruments were 0.74%, 1.65%%7.06 ,%5.45and 18.55% respectively. By improving laboratory quality management the results of hematology analyzer determination may be more reliable than manual methods. The difference among various manufacturers was very small about RBC, Hb, Hct, WBC and Plt the results from all kinds of instruments will tend to be comparable.

1.2.5.2 Previous study in Sudan

Study was done in Sudan by Walaa Mohammed Al-samani at 2009 in two different sysmex filoam connected from Patients who required for routine (CBC) investigation in Khartoum teaching hospital from Research laboratory and Emergency laboratory. The results show that there was in significant variation in the mean of Hb, RBC, HCT, MCV, MCH, RDW-SD, RDW-CV ; (p.value 0.6). (*P.value* 0. 9). (*p.value* 0.2). (*p.value* 0.1). (*p.value* 0.2). (*p.value* 0.4). (*p.value* 0.8) respectively. And there was significant variation in the mean of MCHC

(p.value 0.004). In the results of WBC parameters showed that there were insignificant variation in all WBC results. And in the results of PLts showed that there were insignificant variations in all platelets results.

1.3. Rationale

To avoidance the errors may occur in traditional manual or individual assay methods for hematological parameters and the eye count leukocyte differential. the hematology analyzers provide quick and accurate results in most situations as the initial screening and detection system for hematological abnormalities in modern hospitals and clinics but There are differences in CBC results among different laboratories, and this may be due to the uses of different type of automated instrument for estimation, the environment of the laboratory, and the technical staff which may not evident with genera on of QC system of the different hematological analyzers . No previous studies concerning the determined of CBC by using different hematological analyzers in Sudan.

1.4. Objectives

1.4.1. General objective

To determine of CBC using Three different modern hematological analyzers.

1.4.2. Specific objective

-To measure CBC using hematology analyzers Sysmex Kxn-21 , Digon D-cell60 and Urit 3010.

-To compare the CBC result performed by different automated hematology analyzers .

-To calculate and detect sensitivity ,specificity, and Probability value of the hematological analyzers.

Chapter two

Materials and Method

Chapter two

Materials and Methods

2.1 Study design:

This was a prospective and cross sectional study conducted in period from February to August 2016in Hi Tech Laboratory, Dr. Mohammed Altaib Laboratory and Modern Medical Laboratory in Khartoum State.

2.2 Study population:

Fifty samples from Volunteers were studied to measurement of CBC by automated hematology analyzers Sysmex KX-21N , Digon D-cell 60 and URIT 3010

2.3 Sample collection

Two and half ml venous blood was collected from individuals under study and dispensed in EDTA container for CBC determination in duplicate, hemolysed or clotted blood are excluded.

2.4 Procedure of complete blood count

2.4.1 Hemoglobin, Hematocrit, RBCs count and RBC indices

Automated counting methods for RBC have been based originally on electrical impedance techniques. The hemoglobin concentration is measured optically using the solution in the WBC bath. The lysing agent contains potassium cyanide that reacts with the hemoglobin (Hb) to form cyanmethemoglobin The color intensity ,measured in separate cuvette, is read spectrophotometrically at 540 nm and is proportional to the concentration of hemoglobin. Some instruments use a modified cyanmethemoglobin procedure, and others use cyanide-free colorimetric determinations (Kakkar *et al.*,2009). The Hct is a test that measures

the volume of blood in percent that is comprised of the RBC. Automated cell counters calculate the Hct by multiplying the RBC count by the MCV. The three main RBC indices are used to determine the average size and hemoglobin content of the RBC, and they help to determine the cause of anemia. MCV is the average size of the red blood cells expressed in femtolitres (fl).The MCV is measured by electronic cell counters, usually by dividing the summation of the cell volumes by the RBC count. Mean corpuscular hemoglobin (MCH) is the average amount of hemoglobin inside an RBC expressed in picograms. The MCH is calculated by dividing the hemoglobin concentration by the RBC count. Mean corpuscular hemoglobin concentration (MCHC) is the average concentration of hemoglobin in the RBC. It is calculated by dividing the hemoglobin by the Hct. The mean of the RBC distribution histogram, based on electrical impedance, is the MCV, and the coefficient of variation, or sometimes the standard deviation, is the red cell distribution width (RDW). The RDW provides some insight and quantification into the variation in red cell size, or anisocitosis (Chapman, 2000) .Also some analyzers have generated characteristic red cells cytograms, representing the red cell volume and hemoglobin concentration (V/HC). (Kakkar *et al.*,2009).

2.4.2 Differential Leukocyte Count

Automated differential leukocyte count (DLC) implementation is a more complicated process and has been through several different technologies. The automated analyzer used cell volume to provide a three-part differential analysis: neutrophil, lymphocyte and monocyte cell counts (Barnes et *al*.,2005) The voltage pulses produced by the WBC depend upon the size of the cell and its nuclear density. Therefore, the pulses may be analyzed to differentiate between the types of WBC found. For example, lymphocytes are the smallest WBC and comprise the lower end of the size scale

.Monocytes, pro lymphocytes, and immature granulocytes comprise the central area of the WBC histogram, and mature granulocytes comprise the upper end. (Zandecki .,*et al* 2007) .Hematology instruments use the three-part differential WBC separation .It should be remembered that identification of monocytes, immature myeloid cells and nucleated red blood cells (NRBC) by those instruments is difficult .In general, peripheral smear review is necessary to validate the automated differential generated by the instrument.(Gopal.,*et al*2005).

2.4.3. The Platelet count

The platelet count (PLT) is most often measured by impedance counting. Using this principle PLT and RBC which are both analyzed in the same channel are discriminated according to their volume and volume histograms are generated next. For PLT, the histogram generates alog curve if the distribution of PLT volume its that of a(log) normal distribution: eventually all particles located under the fitted curve are considered as PLT. Mean PLT volume ranges from 2 to 20 fl and, according to the fitted curve, the upper threshold that discriminates PLT from RBC may either be at 36 fl or may vary automatically depending on the characteristics of individual blood sample (Sysmex). Instrument flags are triggered for cases corresponding to in ability to separate clearly PLT from RBC (Zandecki *et al.,* 2007).

2.5 Ethical consideration:

Approve from Scientific Research Committee OF Medical Laboratory Science, Sudan University for Science and Technology.

Peoples who voluntary accepted to participate in the study verbaly were included.

2.6 Statistical analysis

Data were entered, checked and analyzed using Statistical package for social science version 11.5 , Mean ± SD and One Way Anova test were used (*p.value* >0.05).

Sensitivity and specificity were calculated using the formula:

$$\text{Sensitivity} = \frac{\text{True positive}}{\text{True positive + false negative}}$$

$$\text{Specificity} = \frac{\text{True negative}}{\text{False positive + true negative}}$$

Chapter Three

CHAPTER THREE

RESULTS

In total of 50 collected samples, Complete Blood Count was estimated by using three different modern hematological analyzers ,CBC was done on Digon D-cell60(A) ,Sysmex Kxn-21(B) and Urit3010(C) hematological analyzers to measure sensitivity ,specificity, and *P.value* of each one.

The results showed that mean ± SD of hemoglobin on DigonD-cell60, Sysmex Kxn-21, Urit3010 hematological analyzers were 12.13±2.1, 12.53±1.8 and 11.5±1.8, respectively, with statistically significant difference in hemoglobin among different hematological analyzers (*P.value*=0.025).

Mean ± SD of red blood cells on DigonD-cell60, Sysmex Kxn-21and Urit3010 hematological analyzers were 4.53±0.7, 4.67±0.6 and 4.23±0.6, respectively with significance statistically difference between them (*P.value*=0.002).

Regard to mean ± SD Hematocrit on Digon D-cell60,Sysmex Kxn-21and Urit3010 hematological analyzers were 38.9± 6.0, 38.96±5.1and 34.05±5.6 respectively with strong statistically significant difference on HTC results (*P.value*=0.000)

Mean cell volume mean ± SD on Digon D-cell60, Sysmex Kxn-21and Urit3010 hematological analyzers were 85.44±8.4, 82.89±8.5, 80.14±9.9 respectively, there was strongly significant difference in MCV (*P.value*=0.015).

Mean cell hemoglobin mean ± SD showed miner variations in there analyzers associated also with statistical significance 27.88±3.0, 26.54±3.0, 26.92±3.2 (*P.value*=0.085) respectively.

mean ±SD of mean cell hemoglobin concentration in Digon D-cell60 was 32.63±12.0 , while in of Sysmex Kxn-21 was 32.01±1.4 and in Urit3010 was 33.94±2.1 and statistically showed significant difference (*P.value* =0.000).

Red cell distribution width coefficient of variation mean ± SD on DigonD-cell60 was 15.1 ±1.4 , compared with Sysmex Kxn-2114.5 ±2.3 and Urit3010 hematological analyzers was 11.5±2.1 ,with significant difference in it (*P.value*= 000).

Red cell distribution width standard deviation showed slight variation in mean ± SD on Digon D-cell60, Sysmex-Kxn-21 and Urit3010 hematological analyzers 46.41±6.0, 45.33±7.1, 48.75±9.1 respectively with no statistical difference in RDW-SD (*P.value*=0.069) .

Total white blood cells mean ± SD hematological analyzers were 5.89±2.8, 7.44±3.1, 7.53±3.3 respectively, there was significant difference in TWBCs (*P.value*=0.011).

Lymphocytes count results showed that mean ± SD on Digon D-cell60, Sysmex Kxn-21, Urit3010 hematological analyzers were 32.76±13.2, 37.52±14.1, 39.2±13.6, while neutrophils count were 56.44 ±13.3, 49.24±15.5, 51.66±13.9 respectively, with no statistical difference in Lymphocytes count (*P. value*=0.060) , compared with significant difference in neutrophil count (*P.value*=0.040).

Mix count mean± SD Digon D-cell60, Sysmex Kxn-21, Urit3010 hematological analyzers were 10.8±3.0, 13.2±6.9, 9.3±2.6 respectively, there was strongly significant difference in Mix count (*P. value* =0.000) .

Platelet count results showed slight variations in mean ± SD in three analyzers 293.08±87.8, 292.12±98.1 and 260.18±84.8 there was no statistical correlation with them (*P. value* = 0.121).

Platelet indices showed no difference in mean platelet volume mean ± SD on DigonD-cell60, Sysmex Kxn-21, Urit3010 hematological analyzers were 8.0±0.7, 10.75±2.2, 10.57±0.8 respectively, there was strongly significant difference in MPV (*P. value* = 0.000) and there was no change among different hematological analyzer.

Platelet distribution width mean ± SD on analyzers were 15.78±0.7, 13.21±2.0, 12.26±1.4 respectively, with was strongly significant difference in PDW (*P.value*=0.000).

Platelet large cell ratio mean ± SD on Sysmex-Kxn-21, Urit3010 hematological analyzers were 27.69±7.7, 14.47±5.0 respectively, with was strongly significant difference in P-LCR (*P.value*=0.000).

Table 1.3: Show the mean and Standard Deviation of CBC parameters and relation with different hematological analyzers

Parameters	Mean ± SD (A)	Mean ± SD (B)	Mean ± SD (C)	*p. value*
Hemoglobin (g/dl)	12.13 ± 2.1	12.53 ± 1.8	11.5 ± 1.8	0.025
RBCs $\times 10^{12}$/L	4.53± 0.7	4.67 ± 0.6	4.23 ± 0.6	0.002
Hct %	38.91 ± 6.0	38.96 ± 5.1	34.05 ± 5.6	0.000
MCV fl	85.44 ± 8.4	82.89 ± 8.5	80.14 ± 9.9	0.0150
MCH pg	27.88 ± 3.0	26.54 ± 3.0	26.92 ± 3.2	0.085
MCHC %	32.63 ± 1.2	32.01 ± 1.4	33.94 ± 2.1	0.000
RDW-CV%	15.1 ± 1.4	14.5 ± 2.3	11.5 ± 2.1	0.000
RDW-SD %	46.41 ± 6.0	45.33 ± 7.1	48.75 ± 9.1	0.069
TWBCs$\times 10^{9}$/L	5.89 ± 2.8	7.44 ± 3.1	7.53 ± 3.3	0.011
Lymph %	32.76 ± 13.2	37.52 ± 14.1	39.02 ± 13.6	0.060

Neutro %	56.44 ± 13.3	49.24 ± 15.5	51.66 ± 13.9	0.040
MXD%	10.8 ± 3.0	13.2 ± 6.9	9.3 ± 2.6	0.000
PLTs×10^9/L	293.08 ± 87.8	292.12 ± 98.1	260.18 ± 84.8	0.121
MPV fl	8.0 ± 0.7	10.75 ± 2.2	10.57 ± 0.8	0.000
PDW %	15.78 ± 0.7	13.21 ± 2.0	12.26 ± 1.4	0.000
P-LCR %	-	27.69 ± 7.7	14.47 ± 5.0	0.000

Sensitivity measured between Digon D-cell 60 with Sysmex-Kxn-21 for hemoglobin, red blood cell ,Hematocrit , Mean cell volume ,Mean cell hemoglobin, mean cell hemoglobin concentration and red distribution width with standard deviation and Red distribution width coefficient of variation were 82.6% , 97.6% , 96.9% , 86.9% , 69.5% ,74% ,78.7% ,69.6% respectively while measurement of sensitivity between Sysmex-Kxn-21 with Urit 3010 were 54.7% , 87.5% , 62.2% , 91.9% , 93.1% , 36.1% , 76.7% and 82.5 % respectively also measured between Digon D-cell 60 with Urit 3010 were 55.8% ,74.5% ,62.7% ,81.6% ,71.6% , 55.5% ,60.4% and 76.6% the result of sensitivity showed highly sensitive when measured between Digon D-cell 60 with Sysmex-Kxn-21 comparing with others. While the MCV , MCH and RDW-CV were highly sensitive when measured by sysmex-kxn-21 with Urit 3010 hematological analyzers.

Digon D-cell60 with Urit 3010 hematological analyzers showed highly sensitive result in measurement of white blood cell , Neutrophil and MXD count were 97.3% , 97.9% and 95.8% respectively when comparing with Digon D-cell 60 with Sysmex-Kxn-21 were 88% , 95.9% and 68.6 % and sysmex-kxn-21 with Urit 3010 were 87.5% .93.7% and 52% respectively while the lymphocyte count was high sensitivity when measured by sysmex-kxn-21 with Urit 3010 was 95% compared with Digon D-cell60 with Urit 3010 was 93.9% and Digon D-cell 60 with Sysmex-Kxn-21 was 73.8%.

Sensitivity was measurement between Digon D-cell 60 with Sysmex-Kxn-21 for platelet, mean platelet volume and platelet distribution width were showed 97.9% , 53.3% and 84.7% , between sysmex-kxn-21 with Urit 3010 were 97.6% , 97.8%

and 92% and between Digon D-cell60 with Urit 3010 were 100% , 52.1% and 87%.

The sensitivity of Platelet large cell ratio was calculated between sysmex-kxn-21 and Urit 3010 hematology analyzers 86.5%.

Table 3.2 show the sensitivity between the hematological analyzers result

Parameters	A+B	B+C	A+C
Hb g/dl	82.6%	54.7%	55.8%
RBC×10^{12}/l	97.6%	87.5%	74.5%
HCT%	96.9%	62.2%	62.7%
MCVfl	86.9%	91.9%	81.6%
MCHpg	69.5%	93.1%	71.6%
MCHC %	74%	36.1%	55.5%
RDW-CV %	69.6%	82.5%	76.6%
WBC×10^{9}/l	88%	87.5%	97.3%
LYMPH %	73.8%	95.2%	93.9%

NEUTR %	95.9%	93.7%	97.9%
MXD %	68.6%	52%	95.8%
PLT×10^9/L	97.9%	97.6%	100%
MPVfl	53.3%	97.8%	52.1%
PDW %	84.7%	92%	87%
P-LCR %	-	86.5%	-

The specificity was measured by Digon D-cell60 and sysmex-kxn-21 for hemoglobin, Red blood cell ,Hematocrit , mean cell volume , mean cell hemoglobin and Red distribution width with standard deviation and red distribution width coefficient of variation were 88.5% ,90% ,94.7% ,62.5% ,36.3% ,81% ,77.4% and 72.9% respectively , while the specificity between sysmex-kxn-21 and Urit 3010 were 58.6% , 57.1% , 45.9% , 84.2% , 92% , 61.6% , 62.9% and 70.8% respectively . between Digon D-cell60 and Urit 3010 specificity result were showed 67.3% , 39.1% , 48% , 52% , 38.7% , 83.3% , 58.5% and 79.4% respectively this analyzers showed is very low specificity compared with others expect in MCH and RDW-CV.

Digon D-cell60 with Urit 3010 hematological analyzers when measured the specificity of the white blood cell , Neutrophil and MXD count showed highly specific result were 92.8%, 75% and 66.6% when compared with specificity between Digon D-cell 60 with Sysmex-Kxn-21 and sysmex-kxn-21 with Urit 3010 were 72.7% , 60% , 16 % and 57.1% , 62.5% , 52% respectively while sysmex-kxn-21 with Urit 3010 was high specifici result when measured the lymphocyte count was 96.7% compared with Digon D-cell60 with Urit 3010 was 90.4% and Digon D-cell 60 with Sysmex-Kxn-21 was low specificity 63.3%.

The specificity measured for Platelet ,Mean platelet volume and Platelet distribution width between Digon D-cell 60 with Sysmex-Kxn-21 were showed 87.5% ,53.3% and 61.1% respectively this was highly sensitive in PDW , when measured between sysmex-kxn-21 and Urit 3010 were 88.8% ,83.3% ,50% and 100% , 54.1% and 50% when measurement between Digon D-cell60 with Urit 3010.

The specificity of Platelet large cell ratio was 41.6% when measured between sysmex-kxn-21 and Urit 3010 hematological analyzers.

Table 3.3 show the specificity between the hematological analyzers result

Parameters	A+B	B+C	A+C
Hb g/dl	88.5%	58.6%	67.3%
RBC×10^{12}/L	90%	57.1%	39.1%
HCT %	94.7%	45.9%	48.%
MCVfl	62.5%	84.2%	52.6%
MCHpg	36.3%	92%	38.7%
MCHC %	81%	61.6%	83.3%
RDW-CV %	72.9%	70.8%	79.4%
RDW-SD %	77.4%	62.9%	58.5%
WBC×10^{9}/L	72.7%	57.1%	92.8%
LYMPH %	63.3%	96.7%	90.4%
NEUTR %	60%	62.5%	75%

MXD %	16%	52%	66.6%
PLT $\times 10^9$/L	87.5%	88.8%	100%
MPVfl	53.3%	83.3%	54.1%
PDW %	61.1%	50%	50%
P-LCR %	-	41.6%	-

Chapter Four

Discussion, Conclusion, and Recommendations

Discussion, Conclusion, and Recommendations

4.1. Discussion

This study involved 50 blood samples which estimated for routine complete blood count (CBC) investigation in Khartoum State by three different manufactures of hematology analyzers using the same principle Electrical Impedence Technique (Digon D-cell 60 ,Sysmex kxn-21 and Urit 3010) and to observe the deviation among these instruments .

The present study showed that Digon D cell60 ,Sysmex kxn-21 and URIT 3010 were significant in measurement of the mean of hemoglobin, RBC, HCT, MCV, MCHC, RDW-CV ,WBC ,neutrophil ,MXD , MPV ,PDW and PLCR .while there was no statistically correlation in measurement of MCH , RDW-SD ,lymph and PLT by them , this finding agree with (Walaa , 2009) in study represented that the MCH ,RDW-CV ,PLT and lymph result showed that the insignificant variation when using two different sysmex filoam .

Regard to sensitivity and specificity for the Three hematological analyzers showed that the Sysmex kxn-21 is more sensitive and specific in detection of Hb , RBC, HCT ,MCV, MCHC, RDW-SD compared with t Digon D cell60 and Urit 3010 hematological analyzers this agree with (Zhou *et al.*,2009) in study represented the sensitivity was 94.9% and specificity 76.7% of sysmex kxn-21 when compared with hemoglobin photometer in measuring of hb concentration .

The hematological analyzer URIT 3010 showed that was more sensitive and specific in measurement of WBCs and differential count, Plt, PDW and MPV were calculated according to normal rang in Sudan (Abass *et al.*,2016) .

compared with Digon D cell60 and Sysmex kxn-21 hematological analyzers .

4.2 Conclusion:

- There were significant difference in the mean of Hb, RBC, HCT,MCHC, MCV and RDW-SD, TWBC ,neutrophil ,MXD, PDW, MPV, and P-LCR, and no statistically difference in mean of MCH , RDW-CV ,lymphocyte and PLT .

-the hematology analyzers Sysmex kxn-21 is more sensitive and Specific compared with Digon D cell 60 and URIT 3010 in measurement of Hb, RBC, HCT,MCHC, MCV and RDW-SD parameters.

- the hematology analyzers URIT 3010 is more sensitive and Specific than Sysmex kxn-21 and Digon D cell 60 in measurement of WBCs and differential count , Plt ,PDW and MPV.

4.3 Recommendations:

- Importance of using well calibrated instruments and quality control program.
- Continuous training and developing programs for lab workers.

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Appendixes

Appendix (1) Sysmex kxn-21

SYSMEX CORPORATION SN: B7627.

Made in Japan

Appendix (2) :Digon D cell-60

Digon Ltd SN:AC76AA2201

Made in Hungary

Appendix(3) URIT 3010

URIT Medical Electronic Co.Ltd SN: 3010E01744.

Made in China